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07-11613
CLOSED, TRANSF

**U.S. District Court
Western District of Kentucky (Paducah)
CIVIL DOCKET FOR CASE #: 5:07-cv-00199-TBR
Internal Use Only**



Brim et al v. Merck and Company, Inc.
Assigned to: Judge Thomas B. Russell
Cause: 28:1332 Diversity-Personal Injury

Date Filed: 11/26/2007
Date Terminated: 01/07/2008
Jury Demand: Both
Nature of Suit: 365 Personal Inj. Prod.
Liability
Jurisdiction: Diversity

Plaintiff

Lois Brim

represented by **David Randolph Smith**
Law Office of David Randolph Smith &
Edmund J. Schmidt III
1913 21st Avenue South
Hillsboro Village
Nashville, TN 37212
615-742-1775
Fax: 615-742-1223
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CERTIFIED
U. S. DISTRICT COURT
LOUISVILLE, KY.
DATE: 1-7-08
BY: umcelure
Deputy Clerk

Stephanie Ritchie
Baston, Nolan, Williamson, Pearson &
Miller
121 S. Third Street
Clarksville, TN 37040
931-647-1501
Fax: 931-553-0153
Email: sdritchie@batsonnolan.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Plaintiff

Loyd Brim

represented by **David Randolph Smith**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Stephanie Ritchie

(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

V.

Defendant

Merck and Company, Inc.

represented by **Andrew Douglas Dill**
 Woodward, Hobson & Fulton, LLP
 101 S. Fifth Street
 2500 National City Tower
 Louisville, KY 40202-3175
 502-581-8000
 Fax: 502-581-8111
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LEAD ATTORNEY
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Date Filed	#	Docket Text
11/26/2007	<u>1</u>	COMPLAINT against Merck and Company, Inc. Filing fee \$ 350, receipt number 0644000000000631208., filed by Lois Brim, Loyd Brim. (Attachments: # <u>1</u> Cover Sheet) (KJS) (Entered: 11/27/2007)
11/27/2007	<u>2</u>	Case Assignment (Random Selection): Case Assigned to Judge Thomas B. Russell. (KJS) (Entered: 11/27/2007)
11/27/2007	<u>4</u>	Notice sent to Judicial Panel on Multidistrict Litigation re MDL 1789. (KJS) (Entered: 11/28/2007)
11/28/2007	<u>3</u>	Summons Issued as to Merck and Company, Inc. (KJS) (Entered: 11/28/2007)
12/31/2007	<u>5</u>	ANSWER to <u>1</u> Complaint by Merck and Company, Inc.. (Dill, Andrew) (Entered: 12/31/2007)
01/02/2008	<u>6</u>	NOTICE from USDC NYSD. (Attachments: # <u>1</u> Certified Copy of CTO 41) (NM) (Entered: 01/07/2008)

01/07/2008	7	NOTICE from USDC WDKY re <u>6</u> Notice of Transfer to USDC SDNY MDL Court.cc: Counsel, USDC SDNY (NM) (Entered: 01/07/2008)
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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
AT PADUCAH

LOIS BRIM, et vir, LOYD BRIM

Plaintiffs,

VS.

MERCK & CO., INC.,

Defendant.

CIVIL ACTION NO. 5:07CV-199-R

JURY DEMAND

COMPLAINT

Plaintiffs bring this action against Merck & Co., Inc., the manufacturer of Fosamax®. Plaintiff states the following:

1. Plaintiffs Lois and Loyd Brim are citizens of the State of Kentucky. They reside in Hopkinsville, Kentucky. A doctor prescribed Fosamax® to Lois Brim. She took the medication as prescribed. Subsequently, Lois Brim suffered osteonecrosis of the jaw and loss of teeth. Her husband suffered a loss of his wife's consortium.

2. Defendant Merck & Co., Inc. (“Merck”) is a Delaware corporation with its principal place of business located at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey, 08889-0100. Merck’s principal place of business is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.

3. At all times relevant hereto, Merck was in the business of manufacturing, marketing, distributing, testing, labeling and selling Fosamax®.

4. This Court has personal jurisdiction and venue for Merck. Merck markets Fosamax® to physicians in Kentucky so that they will prescribe it to their patients in Kentucky. Merck distributes and sells Fosamax® to patients in Kentucky. Merck compensates agents who pitch the drug to doctors in Kentucky. Merck sends instructional materials about the drug and other Merck products to patients and physicians in Kentucky. Merck profits from health maintenance organizations administered in Kentucky. Patients in Kentucky remit a co-payment to pharmacists when purchasing Merck products. Merck profits from patients in Kentucky who use its medication. Merck resides in Kentucky through its agents.

5. Venue is proper in this judicial district under 28 U.S.C. § 1391.

6. The amount in controversy exceeds \$75,000 exclusive of costs and interest, and diversity jurisdiction exists pursuant to 28 U.S.C. § 1332.

Factual Background

7. Fosamax® is a bisphosphonate. The principal pharmacological action of Fosamax® is inhibition of bone resorption. Bisphosphonates prevent and treat osteoporosis in post-menopausal women. Stronger forms of bisphosphonates are used in the management of cancers. Taking Fosamax® increases the risks of osteonecrosis of the jaw, including the maxilla bone. Taking Fosamax® can cause osteonecrosis of the bone.

Count 1 – Strict Liability

8. Merck was in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packing, supplying, marketing, selling, advertising, warning, and

otherwise distributing Fosamax® in interstate commerce, which they sold and distributed throughout the world. Therefore, Merck is the manufacturer and this is a product liability action.

9. Lois Brim was taking Fosamax® in a reasonably foreseeable manner.

10. Fosamax® is unreasonably dangerous and defective due to defective design and defective and/or inadequate warnings. This unreasonably dangerous and defective drug increased the risk of osteonecrosis and other damage to her jaw and teeth.

11. Mrs. Brim suffered injury and damage to her jaw and teeth. She has sustained compensatory damages in an amount to be proven at trial not in excess of the jurisdictional limits of this Court.

12. Merck also acted recklessly or with gross negligence. Plaintiff therefore seeks the award of punitive damages.

Count II - Negligence

13. Merck owed Mrs. Brim a common law duty to use reasonable care in the manufacturing, creating, designing, testing, labeling, sterilizing, packing, supplying, marketing, and advertising Fosamax®. This included a duty to warn about the dangers of bisphosphonate-induced osteonecrosis. Merck breached that duty of care in one or more of the following respects:

- a) Failing to test and inspect Fosamax® in a reasonable manner in order to ascertain whether or not the drug was safe and proper for the use for which it was designed, manufactured and sold;

- b) Failing to utilize and implement a reasonably safe design;
- c) Failing to manufacture Fosamax® in a reasonably safe condition;
- d) Failing to warn of the dangers of bisphosphonate-induced osteonecrosis and other injury;
- e) Failing to label Fosamax® reasonably so as to warn physicians, pharmacists, and Mrs. Brim of the danger of bisphosphonate-induced osteonecrosis and other injury; and
- f) Manufacturing Fosamax® in an unreasonably dangerous and defective condition.

14. Furthermore, Merck is guilty of negligence per se by violating the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq.

15. Merck failed to meet the standard of care set forth in the following statutes and regulations, which statutes were passed to benefit a specific class of citizens and Plaintiff is within this class, therefore, Merck is guilty of negligence per se:

- a) The labeling lacked adequate information on the use of the drug Fosamax® (21 C.F.R. § 201.56(a) and (d)).
- b) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. § 201.57(e)).

- c) There was inadequate information for patients for the safe and effective use of Merck drugs (21 C.F.R. § 201.57(f)(2)).

16. Merck's negligence was the proximate cause of all damages. Mrs. Brim has suffered injury including but not limited to pain, swelling and loss of teeth. She has sustained compensatory damages in an amount to be proven at trial.

17. Plaintiff Loyd Brim has suffered the loss of spousal consortium as a direct result of Defendant's wrongful acts.

WHEREFORE, Plaintiffs request that a jury be impaneled and that this Court award compensatory and punitive damages in an amount specified by the jury, and Mr. Brim seeks an award from that same jury for the loss of his spousal consortium.

Respectfully Submitted,

Batson, Nolan, Williamson, Pearson & Miller

By: s/ Stephanie D. Ritchie
Stephanie D. Ritchie, TN Bar #024883
KY Bar #87104
121 South Third Street
P.O. Box O
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David Randolph Smith, TN Bar #011905
Of counsel, pro hac vice pending
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e-mail: drs@drslawfirm.com



Case Assignment Standard Civil Assignment

Case number **5:07CV-199-R**

Assigned : Judge Thomas B. Russell
Judge Code : 4413

Assigned on 11/27/2007

[Request New Judge](#) [Return](#)

UNITED STATES DISTRICT COURT

Western District of Kentucky

Lois Brim, et vir, Loyd Brim

SUMMONS IN A CIVIL ACTION

V.

Merck & Co., Inc.

CASE NUMBER: 5:07-CV-199-R

COPY

TO: (Name and address of Defendant)

Merck & Co., Inc.
c/o Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Stephanie D. Ritchie
Attorney for Plaintiffs
121 S. Third Street
Clarksville, TN 37040

an answer to the complaint which is served on you with this summons, within 20 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

JEFFREY A. APPERSON

CLERK

DATE

11/27/2007

(By) DEPUTY CLERK

John Sparking

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

- ☐ Served personally upon the defendant. Place where served:
- ☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left:
- ☐ Returned unexecuted:
- ☐ Other (specify):

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL \$0.00
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DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____
Date

Signature of Server

Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

Office of the Clerk,
Room 127, 501 Broadway
Paducah, Kentucky 42001-6866
270-415-6400
www.kywd.uscourts.gov

Jeffrey A. Apperson
Clerk of Court

Vanessa Armstrong
Chief Deputy Clerk

November 27, 2007

Judicial Panel on Multidistrict Litigation
One Columbus Circle, N.E.
Federal Judiciary Building
Room G-255, North Lobby
Washington, D.C. 20002

IN RE: MDL -1789

To Whom It May Concern:

Enclosed please find copies of the docket sheet and complaint filed in our district on November 26, 2007. We believe that these actions are related to MDL 1789.

If you need any further information, please feel free to contact me at 270-415-6408.

Very truly yours,

JEFFREY A. APPERSON, CLERK

BY: s/ Kelly Sherrard
Deputy Clerk

Enclosures

ELECTRONICALLY FILED

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT PADUCAH

LOIS BRIM, <i>et vir</i> , LOYD BRIM)	
)	
PLAINTIFFS)	
)	
v.)	CIVIL ACTION NO. 5:07CV-199-R
)	
MERCK & CO., INC.,)	
)	
DEFENDANT.)	

ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC.

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first, second, third and fourth sentences of Paragraph 1. Merck denies the remaining allegations of Paragraph 1.
2. Merck denies each and every allegation of Paragraph 2, except that it admits that Merck has its principal place of business in New Jersey.
3. Merck denies each and every allegation of Paragraph 3, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.
4. The allegations in the first sentence of Paragraph 4 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies the allegations in the first sentence of Paragraph 4. Merck denies the remaining

allegations of Paragraph 4, except that Merck admits that it marketed and distributed FOSAMAX® for prescription in accordance with its approved prescribing information.

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 5.

6. Merck is without knowledge as to the allegations in Paragraph 6 regarding the amount in controversy, but for jurisdictional purposes only, admits that the Plaintiffs seek in excess of \$75,000. Merck denies the remaining allegations of Paragraph 6.

Factual Background

7. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 7 inconsistent with that prescribing information. Merck respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 7.

Count 1 – Strict Liability

8. Merck denies each and every allegation of Paragraph 8, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and that Plaintiffs purport to bring a product liability action.

9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 9.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies the allegations contained in the first sentence of Paragraph

12. As to the allegations of the second sentence of Paragraph 12, Merck admits that Plaintiffs seek punitive damages, but denies that there is any legal or factual basis for same.

Count II – Negligence

13. The allegations in the first and second sentences of Paragraph 13 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules. Merck denies the remaining allegations of Paragraph 13, including each and every allegation contained in subparts (a) through (f).

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15, including each and every allegation contained in subparts (a) through (c).

16. Merck denies each and every allegation of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

Merck denies that Plaintiffs are entitled to any of the relief requested in their Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiffs' Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned.

EIGHTH AFFIRMATIVE DEFENSE

The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or in part from their own comparative negligence and any damages recovered should be reduced accordingly.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or

exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability

because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Kentucky Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs'

claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Kentucky applies to Plaintiffs' claims.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Merck is entitled to the benefit of the presumption of non-defectiveness provided in the Kentucky Product Liability Act, KRS 411.310(2).

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Merck asserts all defenses available under the Kentucky Product Liability Act, KRS 411.300 *et seq.*

In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,

s/ Andrew D. Dill
Richard H. C. Clay
Andrew D. Dill
WOODWARD, HOBSON & FULTON, L.L.P.
2500 National City Tower
Louisville, Kentucky 40202
(502) 581-8000
Counsel for Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 31, 2007, I electronically filed the foregoing Answer and Affirmative Defenses of Merck & Co. with the Clerk of the Court by using the CM/ECF system. I hereby further certify that on December 31, 2007, a copy of the foregoing was served upon the following by first class mail, postage prepaid:

Stephanie D. Ritchie
Batson, Nolan, Williamson, Pearson & Miller
121 South Third Street
P.O. Box O
Clarksville, Tennessee 37040

David Randolph Smith
1913 21st Avenue South
Nashville, Tennessee 37212

Attorneys for Plaintiff

s/ Andrew D. Dill
Richard H. C. Clay
Andrew D. Dill

UNITED STATES DISTRICT COURT
Southern District of New York
Office of the Clerk
500 Pearl Street
New York, N.Y. 10007
(212)805-0136

FILED
Jeffrey A. Apperson, Clerk
JAN 02 2008
U. S. DISTRICT COURT,
WEST'N. DIST. KENTUCKY

J. Michael McMahon
Clerk

USDC WD OF KENTUCKY

Date:
12/28/07

In Re: FOSAMAX

MDL 1789

Your Docket #

5:07-199

S.D. OF N.Y.

07 CV 11613

Dear Sir:

Enclosed is a certified copy of the order of the Judicial Panel on Multidistrict Litigation, transferring the above entitled action presently pending in your court, to the Southern District of New York and assigned to Judge KEENAN for coordinated or consolidated pretrial processing pursuant to 28 USC 1407.

Please return the copy of this letter when transmitting YOUR FILE and a CERTIFIED COPY OF THE DOCKET SHEET.

Sincerely,
J. Michael McMahon

By:
MDL Unit

A CERTIFIED TRUE COPY

DEC 20 2007

ATTEST
FOR THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATIONUNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

DEC - 4 2007

FILED
CLERK'S OFFICE**07 CV 11613**FLD
SD of NY
12/28/07**IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION**Lois Brim, et al. v. Merck & Co., Inc.,
W.D. Kentucky, C.A. No. 5:07-199

MDL No. 1789

CONDITIONAL TRANSFER ORDER (CTO-41)

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 105 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the action on this conditional transfer order involves questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), this action is transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:


 Jeffrey N. Lüthi
 Clerk of the Panel

Inasmuch as no objection is
pending at this time, the
stay is lifted.

DEC 20 2007

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION